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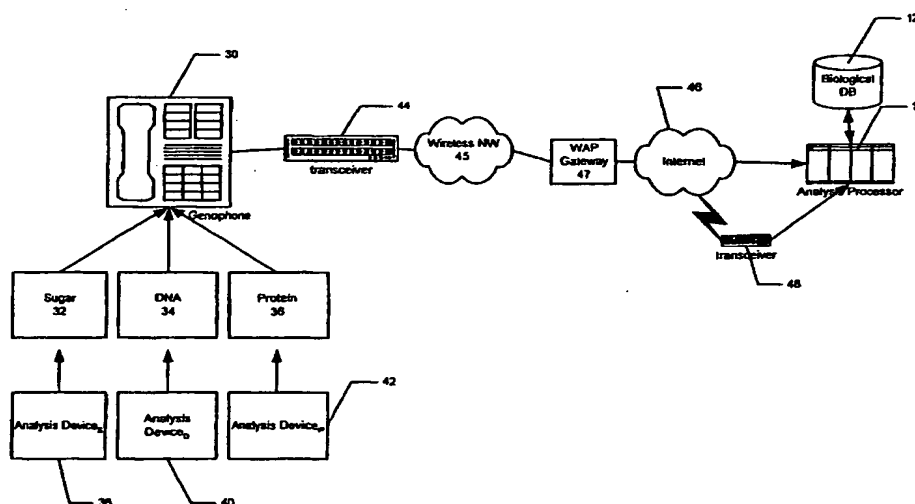
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(54) Title: **SYSTEM AND METHOD FOR GENOMIC AND PROTEOMIC ANIMAL DISEASE ASSESSMENT VIA EXPRES-
SION PROFILE COMPARISON**



(57) Abstract: A system and method of genomic and proteomic animal disease assessment via expression profile comparison whereby a baseline expression profiled is created by a user by depositing a biological sample on an analysis device. The biological information is read on an analysis device reader and transmitted to an analysis center where it is stored. The user deposits subsequent biological samples, which are compared to the stored sample that is originally taken. The analysis center compares the initial expression profile with subsequent expressions profiles to determine the health of the source of the sample. The biological sample can be from animals. The analysis device reader can be a wired or wireless device connected to a personal computer which in turn is connected to the Internet. In an alternate embodiment, the analysis device reader is in a cellular type telephone for wireless transmission. In yet another embodiment, the analysis device reader is in a kiosk which dispenses analysis devices and where it can be used by anyone with a credit token. Interpreted information is then returned to the appropriate person with advice on the meaning of the interpreted results, other sources of expert assistance and counseling where necessary.

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Title of Invention: System and Method for Genomic and Proteomic Animal Disease
Assessment via Expression Profile Comparison

Field of the invention

This invention relates generally to genomic or proteomic testing. More particularly this invention provides a system and method for measuring the expression of the genome and other biological factors over a network, which could lead to disease prediction and prevention in animals.

Background Of The Invention

Mapping of the animal genome has been in process by both the government and private industry for the past ten years. At the same time new research has lead to specific tests for conditions that are evidenced by genes and certain gene expressions. Further the methods for the detecting of genomic, proteomic and other biological factors have dramatically improved.

Similarly, genetic engineering and research is extremely active in the animal marketplace where both plants and animals are the subject of genetic engineering and commercialization.

Research is rapidly progressing on DNA chips from, for example, Affymetrix, and RNA and protein chips available from, for example, Ciphergen which will allow genes, their expression and proteins to be identified on a particular chip. Further Micro Arrays such as those of Nycomed Amersham / Amersham Pharmacia Biotec allow gene detection via very small detectors, thereby reducing the size of the overall detector package. Further, advances in fiber optic probes for example by Illumina, Inc. now allow 250,000 discrete sensors to fit on a probe the diameter of a pin head for proteomic studies. For purposes of this application, such chips, arrays and probes are referred generally as "Analysis Devices." Other similar technologies are available from PE Biosystems, Nycomed Amersham, Nanogen, Hyseq, Caliper, Clinical Micro Sensors. Specifically, Nanogen possesses electronic concentration and hybridization technology that is suited to the present invention. Such technology

1 is embodied in a disposable cartridge comprising a semiconductor microchip and
2 electrical and fluidic connections for use in analysis equipment. The following U.S.
3 patents discuss this technology, the contents of the below listed patents are
4 incorporated herein by reference in their entirety:

5 U.S. Patent No. 6,099,803 "Advanced active electronic devices for molecular
6 biological analysis and diagnostics "

7 U.S. Patent No. 6,071,394 "Channel-less separation of bioparticles on a
8 bioelectronic chip by dielectrophoresis "

9 U.S. Patent No. 6,068,818 "Multicomponent devices for molecular biological analysis
10 and diagnostics"

11 U.S. Patent No. 6,051,380 "Methods and Procedures for Molecular Biological
12 Analysis and Diagnostics"

13 U.S. Patent No. 6,048,690 "Methods for Electronic Fluorescent Perturbation for
14 Analysis and Electronic Perturbation Catalysis for Synthesis "

15 U.S. Patent No. 5,849,486 "Methods For Hybridization Analysis Utilizing
16 Electronically Controlled Hybridization"

17 U.S. Patent No. 5,605,662 "Active Programmable Electronic Devices for Molecular
18 Biological Analysis and Diagnostics"

19 Other analysis techniques also exist and are suitable for use with the present
20 inventions. For example, patent no. 6,045,676 was issued to Mathies et al. for a
21 "Electrochemical detector integrated on microfabricated capillary electrophoresis
22 chips" for use in detecting molecules. The contents of this patent are incorporated
23 herein by reference in its entirety.

24 The LabCD manufactured by Gamera Bioscience Corp. also represents
25 technology that is suitable to sample preparation that would find use in the present
26 invention. The capabilities and format of the LabCD are described in U.S. Patent
27 No. 6,063,589 which is incorporated herein by reference in its entirety.

1 It is yet another objective of the present invention to create a standard
2 expression map for animals that are to be monitored using an analysis device so that
3 expression of every gene and other biological factors can be identified and compared
4 with previous samples from the same monitored animal.

5 It is a further objective of the present invention to characterize gene
6 expression or other biological indicators at a disease stage for comparison to a
7 "standard" expression profile for animals.

8 It is yet another objective of the present invention to characterize the
9 expression of an animal's individual expression profiles periodically during the life
10 span of an animal to be monitored and to store that data on a dedicated site for
11 subsequent review and comparison.

12 It is a further objective of the present invention to have an individual analysis
13 device read at a convenient site, at a site other than a laboratory, in public places,
14 and in hand held devices and have that information transmitted to a central analysis
15 site over a network which could be the Internet, an intranet, a wireless network or
16 some other network able to transmit data.

17 It is still another objective of the present invention to collect expression profile
18 information together with demographic and medical history information to produce a
19 database relating to expression patterns and variation to phenotype state and
20 prognosis.

21 It is a further objective of the present invention to have an Internet analysis
22 site and database of the selected animal genomes, metabolism maps, clinical data
23 and other biological indicators and conditions with conclusions and interpretations
24 associated with the differential expression of certain genes and other biological
25 parameters.

26 It is yet another objective of the present invention to allow responsible
27 individuals to collect and digitize (or render in some other transmittable form) sample
28 I expressions profiles (or other biological information) at home, or at some
29 convenient site such as a veterinary's office, or via some hand held device to provide

1 These analysis devices can then be used to determine if the particular gene in
2 question is working properly with other genes, or if other biological factors are
3 present which may be indicative of certain medical conditions.

4 These devices can also be used to map animal genome and to develop
5 understanding regarding how they are expressed in a body or in body fluids (for
6 example, blood, urine, saliva, sperm, sweat and milk). For example it would be very
7 useful for pet owners, ranchers, people caring for animals, but not limited to such
8 individuals, (responsible individuals) to obtain an animal's expression profile of an
9 animal's genes so that it can be used for assessing an animal's normal versus
10 abnormal condition states. If, for example, a responsible individual knows the
11 difference between the normal expression of genes and the deviations from normal
12 which are statistically important, that could prevent for example, skeletal
13 malformations, dysplasia, heart disease, and other conditions that are reflected by a
14 mutated gene. It would also be useful if a responsible individual would have the
15 expression profile which would be a baseline or standard, for subsequent
16 comparison of normal versus abnormal conditions. Since household pets constitute
17 a billion dollar industry requiring disease assessment and cure such profiles become
18 useful for pet owners.

19 **Summary Of The Invention**

20 It is therefore an objective of the present invention to produce a specific tool in
21 the form of a genophone, a computer with associated reader, and a standalone
22 station which will read an analysis device which will, in turn, measure the expression
23 of genes and other biological parameters in the blood, urine, saliva, sperm, sweat
24 and milk of animals.

25 It is a further objective of the present invention to establish a baseline of the
26 gene expression, and expression of other biological actors such as, but without
27 limitation, small molecules, peptides, and metabolites of an animal when the animal
28 is healthy.

1 tags (ESTs) or RNA molecules or their fragments as well as proteins or their
2 fragments. Other detector devices will have similar mechanisms for detecting the
3 biological indicator of interest. Other types of devices include, and without limitation,
4 a "lab-on-a-chip" with microchannel separation of biological materials (DNA, RNA,
5 protein, hormone, small molecule, peptide, metabolite) with subsequent
6 electrochemical or electric, such as those of Clinical Micro Sensors or optical, such
7 as those of PharmaSeq detection. Such technology also includes 3D silicon
8 particles of cubic or spheric shape, which could carry detection molecules (DNA,
9 RNA, antibodies). The amplification via polymerase chain reaction (PCR) or other
10 methods may be required for enhancing the strength of the signal in biological
11 sample.

12 These above methods are not meant as a limitation. For example,
13 immunoassays, small molecule sensors for metabolites, peptides, hormones and
14 other measures are also within the scope of the present invention. The emphasis in
15 all cases however, is to measure these response variables and record the status at a
16 variety of times in the lifespan of the animal so that predictions of future health can
17 be made.

18 The expression or recording of these biological indicators can then be
19 digitized or put in some other transmittable form at home or at a convenient location
20 on the analysis device reader or other device to make the genetic expression or
21 recording of biological indicators of the individual in the form that is transmittable via
22 the network. Based on the reading, a digitized record of the expression profile of the
23 genome of the animal, which includes transcriptome (all molecules of RNA
24 expressed in the cell as well as in the body), proteome (i.e. the proteome is the
25 summary of all proteins) or other biological indicator is then created. As part of the
26 present invention, the hand held device or computer attached device or real time
27 monitoring station will detect genetic variations of the animals, including, but not
28 limited to, Single Nucleotide Polymorphisms (SNPs) as well as genetic variations in
29 genes of another nature. Those will be compared for a particular an animal over

1 that digitized individual expression profile (or other biological information) over a
2 network to a central analysis site, and to have that analysis site provide an
3 interpretation of an animal's expression profile with conclusions regarding the
4 animal's condition.

5 It is yet another objective of the present invention to provide an analysis tool
6 comprising a browser and analyzer that will allow the data to be transmitted to the
7 analysis site, analyzed according to the animal's standard expression data stored in
8 a specific biological database, and to have a response generated to be sent to the
9 pet owner in a electronic, magnetic, written or audio form so that such persons can
10 get results of the analysis right away on the comparison and differences from the
11 standard expression profile. These and other objectives for the present invention will
12 become apparent from a detailed review of the specification that follows.

13 The present invention comprises a plurality of analysis devices and other
14 detection means that can be produced and distributed to responsible individuals and
15 professionals in the veterinary sciences in great quantities. It is the intention of the
16 present invention to produce such analysis devices in sufficient quantities so that
17 they can be made available to all who desire them in a cost effective fashion. Over
18 time it is expected that the cost of such analysis devices will decrease dramatically
19 and therefore allow analysis devices to be available to anyone desiring to
20 characterize the expression of their genome or other biologically related information.

21
22 These analysis devices are used by a responsible individual for determining
23 an animal's control or "standard" expression profile of an animal's genes or other
24 biological indicators that are to be monitored. A sample of blood, saliva, or urine is
25 obtained and placed in / on the analysis device. The analysis chip, for example,
26 contains probes for animal genes linked to the surface of the chip. Such chips are
27 capable of detecting the presence of other nucleic acids (specifically messenger
28 RNA), which are present in the solution via homology hybridization. Analysis Chips
29 may contain small fragments of the genes (oligonucleotides) or expressed sequence

1 time – giving a chance to build a time-correlation of the progression of the disease.
2 Clinical data will be used to compare populational data of norm versus disease.
3 SNPs could be detected in devices developed by Hyseq or Sequenom, or other
4 manufacturers.

5 Genetic variation noted above can be accomplished on a general basis where
6 many genes are detected and analyzed or, when suggested via background or family
7 history, on a specific SNP analysis based upon expression work done previously.
8 This could be done at the home or at an analysis station or at a regional laboratory.

9 As part of the present invention, an analysis and database site exists on a
10 network, preferably but without limitation on the Internet, that has extensive
11 information on the animal genome and the meaning of various genetic expressions
12 and mutations as well as metabolism maps. A veterinary professional wishing to
13 have an animal's expression profile reviewed, read, and interpreted will send a
14 digitized record created at the analysis device reader over the Internet, or via some
15 other wired or wireless network to the analysis site. The software routines for
16 analysis and interpretation at the analysis site will then read the digitized or
17 transmittable record and interpret that record providing feedback to the responsible
18 individual over the Internet, over an intranet, a wireless network or via any other
19 means (such as voice) for conveniently reporting such information to the responsible
20 individual. A standard PC could also be used for storage and interpretation as well
21 as warning the veterinary professional.

22 Such an invention can also be used to simply provide an expression profile for
23 an animal when that animal is healthy. This "standard" or "baseline" gene
24 expression profile is then stored at the analysis site for later use. This will be
25 important since expression of genes varies with disease and also varies over one's
26 lifetime. Further when an animal is not healthy, that animal can create a new gene
27 expression profile, read and digitize the Analysis device results, provide the results to
28 the analysis site over the Internet, or to a standard PC, compare the digitized results
29 to that animal's baseline or standard expression profile, and make some

1 determination on what has changed and what the impact of that change actually is.
2 Once information is developed based on the gene expression profiles, analysis
3 results can be reported to the field where corrective action can take place. Analysis
4 of results prior to reporting is accomplished by organizations having databases
5 specific to the species involved.

6 It is realized that certain regulatory issues arise with such advice. Where this
7 is the case, information can also be provided to a veterinarian professional for
8 analysis and discussion with the responsible individual.

9 The control gene expression profile or other biological characteristics will also
10 have other uses. From time to time, over a period of years, an animal can provide a
11 new series of digitized or otherwise recorded biological indicators to the analysis site
12 central database and determine how the animal's expression profile is changing.
13 This may suggest certain interventions on the part of the pet owner.

14 The present invention provides for a flexible series of methods and associated
15 apparatus allowing responsible individuals to create a record of the animal's gene
16 expression (RNA and protein) to broaden profiles and other genomic and biological
17 information in a convenient fashion. For example, one embodiment of the present
18 invention provides for an analysis device reader to be attached or connected to the
19 responsible individual's PC for subsequent reading and providing information over a
20 network, which is preferably, but without limitation, the Internet. In another
21 embodiment, analysis device readers may be located in veterinarians' offices to
22 provide such information for subsequent analysis when a personal computer and
23 analysis chip reader is not available.

24 Yet another alternate embodiment allows for a single purpose analysis device
25 reader, which can provide genetic information over a network. Such a device may be
26 a single purpose device optimized to look for a specific gene, metabolite or other
27 indicator of a condition. Yet another alternate embodiment allows for the wireless
28 presentation of analysis device information over a radio network, for example over a
29 cellular network. In this alternate embodiment a form of wireless or cellular type

1 device, hereinafter referred to as a genophone, allows genetic or other biological
2 information to be provided over wireless and/or cellular type networks to an analysis
3 center.

4 Yet another alternate embodiment of the present information allows for a
5 kiosk type operation whereby an analysis device dispenser is located in a public
6 area, such as a mall, or hospital or indeed any other public area. In use, a
7 responsible individual would simply use a credit card or, preferably a smart card
8 having specific encrypted identification information, that is linked to a credit card
9 processing company such as American Express®, VISA®, MasterCard®, or other
10 for billing services. The responsible individual simply inserts the credit/smart card
11 and, after credit verification, would receive an analysis device upon which a
12 biological sample, from an animal could be deposited. The analysis device would
13 then be read by the kiosk analysis device reader and information from the reading
14 sent to the analysis site. Thereafter, the responsible individual can enter information
15 either at the kiosk location or, using coded information that is present on the smart
16 card, the responsible individual can cause the results of the analysis to be sent to the
17 responsible individual via the US Mail, via electronic mail, or via any other selected
18 delivery service which the user prefers including voice transmission to a selected
19 telephone number or voice mail. In any case, such information is sent to the person
20 involved together with information on how to locate source to assist in proper
21 interpretation or the data. In certain instances, identification of counseling and
22 scientific resources would also be identified depending upon the outcome or
23 projected outcome to help the responsible individual understand the results received.

24 The present invention also comprises a genome and health information-
25 specific encrypted browser for a responsible individual to use. This browser, when
26 used with the personal computer or in use with video phones or the like, allows
27 genomic and other biological information from the responsible individual to be
28 appropriately delivered directly to an analysis site as well allows rapid and encrypted
29 access to specific medical and gene analysis sites. In this fashion responsible

1 individuals will not need to expend significant effort in browsing the World Wide Web
2 for information to support conclusions or preliminary analyses made concerning the
3 animal's gene expression profile. Using the encrypting browser, the responsible
4 individual can access a database of genomic and other biological information of the
5 present invention that comprises the control expression profiles of the animal and
6 management of the animal's medical information, all of which will be encrypted.
7 However, in addition there will be a database of metabolic pathways, which will be
8 used to characterize the protein or other expression molecules and characterize and
9 tell what role the protein that is detected has in the overall health of the animal. It is
10 part of the present invention to develop a secure bank-type of mechanism, which will
11 allow for the secured transaction of the genomic and proteomic information by
12 responsible individuals. Such a facility could be established with a partner (i.e.
13 American Express).

14 An animal genome sequence comparison database is also a part of the
15 present invention and allows animal control expression profiles as well as
16 subsequent expression profiles to be compared to various standard expression
17 profiles for analysis purposes.

18 Further, the database will contain subsequent databases and/or links to
19 clinical data, clinical trials in practice, "live" consulting with experts as well as chat
20 rooms to discuss with other responsible individuals genomically, biologically, and
21 medically important information.

22 In addition to these above databases, the database of the present invention
23 comprises Single Nucleotide Polymorphisms (SNP), DNA sequencing, protein-
24 protein interactions and protein-drug interactions so that responsible individuals who
25 generate an animal's expression profile (protein and other molecules) can review
26 what potential drug interactions might be specific for that animal.

27 Any information that a responsible individual wishes to store that is particular
28 to the responsible individual's concern (about animals, such as past illnesses,
29 accidents, or allergies) can be stored in the individual storage area of the database in

1 an encrypted form so that only the responsible individual who has placed that data in
2 the database can have access to the data.

3 The genophone described above will have a series of capabilities. For
4 example it will be able to read DNA or RNA using an appropriate DNA or RNA chip
5 and transmit that information over the wireless network to the analysis center. These
6 chips mentioned above are not meant as a limitation. Other analysis devices as
7 noted earlier will provide for other clinical targets as well such as peptides, hormones
8 and metabolites. Further, the genophone will have a separate protein analysis
9 cartridge, including those which could have antibodies, enzymes or other protein
10 detection systems and separate sugars (or other biological molecules specific for
11 animals) analysis cartridge each of which will be capable of receiving the associated
12 device for deposit of a sample and analysis of the proteins, sugars and other
13 metabolites as appropriate. It is further anticipated that these cartridges could
14 integrated in one single cartridge or unit. This "cartridge" can be a variety of forms
15 and the form is not meant as a limitation. In other forms it employs the various
16 detection technologies discussed (above). For example, the cartridge may be an
17 attachment to the genophone, or it may be its separate instrument or device with its
18 own communications capability for providing information over a network. Cartridge
19 may have different sets of detection mechanisms specific for a particular gene of the
20 gene product or group of genes and their products, which could lead to different
21 types of diseases, (i.e., a cartridge for monitoring gene expression which could lead
22 to heart disease, diabetes or cancer). Cartridges with different types of disease
23 "preventive" expression and other monitoring could combine different types of
24 diseases on one cartridge.

25 In addition, specific disease state monitoring can be accomplished by the
26 equipment of the present invention. Thus monitoring diabetes, heart disease and
27 other conditions can be monitored. Health care state during the course of drug
28 delivery can also be monitored so that the treating veterinary professionals can
29 assess the efficacy of the treatment and the extent to which treatment should

1 continue. Where the therapeutic range of a drug with the patient's system is narrow,
2 such monitoring of the present invention will greatly assist the veterinary professional
3 in monitoring and administering the drug in question as well as to monitor for adverse
4 drug reactions.

5 Expression analysis of the type disclosed with the present invention is well
6 within the current state of the art. For example, a GeneChip™ is an analysis probe
7 array manufactured by Affymetrix® which can detect mRNA transcripts at a few
8 copies per cell. It can also identify concentration levels and simultaneously monitor
9 thousands of genes. This GeneChip™ system is typically scanned by an HP
10 GeneArray scanner to view an expression analysis. Yet another potential technology
11 for analysis is the Assembled Array™ manufactured by Illumina, Inc. This array
12 provides thousands of sensors to analyze DNA, RNA, and protein. Yet another
13 example of chip analysis technology is the ProteinChip™ which is available from
14 Ciphergen. Other analysis devices such as the GeneChip™ instrument system, also
15 available from Affymetrix which provides a platform for analyzing GeneChip probe
16 arrays. In short, certain of the building blocks are readily available for the present
17 invention.

18 **Brief Description Of The Figures**

19 Figure 1 illustrates the overall architecture of the present invention

20 Figure 1A illustrates the stand-alone analysis device reader

21 Figure 2 illustrates the genophone embodiment of the present invention

22 Figure 3 illustrates the kiosk embodiment of the present invention

23 **Detailed Description Of The Invention**

24 The present invention is a system and method for creation of expression
25 profiles of animals, establishing a control expression profile for an animal, and
26 comparing subsequent expression profiles to the control expression profile for
27 analysis purposes. For purposes of this detailed description of the invention, the
28 procedures when dealing with animal genomic information will be discussed. Any
29 reporting that is done will be in terms of the animal in question.

1 Referring to Figure 1, responsible individuals will initially provide a control
2 biological sample, of the animal, on analysis devices **22, 24,**and **26**. The analysis
3 devices will be input to analysis device readers **16**, which, in one instance are
4 connected to PCs **14, 20** at user locations. It is also considered to be within the
5 scope of the present invention to have an analysis device reader / communicator **28**
6 which is a stand-alone unit that reads analysis device **26** and provides that
7 information over the Internet **18** or some other wired or wireless network adapted to
8 convey such information or analyze the biological sample "on the spot" providing
9 limited read out of the presence and / or quantity of the expression of gene or other
10 biological factors, for example and without limitation, particular proteins and their
11 amount (See Figure 1A below). For example, an intranet may be constructed to
12 send and receive such information among a variety of sites at a hospital, or other
13 large organization. For example, a ranch has particular interest in the health and
14 welfare of its livestock. Such an organization would not necessarily use the Internet
15 but would use its own network for the transmission of such gene expression
16 information. In other situations, a cellular network may be used to transmit the
17 desired information when measurements are taken away from the ranch. Analysis
18 device reader **16** reads analysis devices **22, 24** and presents a digitized, or otherwise
19 transmittable record of the individual gene expression or other biological information
20 to the PC **14, 20** at the users location. It should be noted that the "users" location
21 may be a home based unit or a unit at a convenient location such as a veterinarian's
22 office. These PCs will further comprise software for communicating with the analysis
23 site.

24 It is anticipated that connections to the Internet for reporting of these gene
25 expression readings will be both wired as in the case of processor **20** connecting to
26 Internet **18** and wireless as in the case of processor **14** connecting to a wireless
27 fashion to Internet **18** or via other wireless special purpose devices optimized for the
28 expression profile reporting of the present invention.

1 The expression profiles will then be provided to an analysis site **12** over a
2 network such as, and without limitation, the Internet **18** and stored in database **10**
3 identifying the record only in a numeric fashion in order to preserve the unanimity of
4 the individual providing the information. The responsible individuals can report as
5 many different gene or other biological expressions as desired since those
6 expressions will vary by the time of day, over a period of years, and with the
7 changing of an animal's conditions.

8 Analysis site **12** receives the information from each responsible individual and
9 based upon expression, protein, messenger RNA etc. detected, analyze and
10 compare those results to information stored in the biological database. The analysis
11 site **12** can create a reading of the expression profile of the animal together with an
12 interpretation of any particular conditions that might exist.

13 Information relating to the interpretation of the expression profile of the animal
14 is then provided by analysis site **12** over the Internet **18** back to the responsible
15 individual's processor **14, 20** for the responsible individual's information.
16 Alternatively, information from the interpretation of the genomic expression can be
17 provided to the user via mail.

18 It is expected, that as analysis device prices decrease, such analysis devices
19 will be readily available at a reasonable cost to all responsible individuals who desire
20 to use this process. Furthermore, it is also expected that each animal's genes will be
21 sequenced (all or in part) which will allow the creation of the "Individualized Analysis
22 Devices." Those will be used not only to establish controls and to obtain the genome
23 expression reading, but to track any changes in the animal's genes. The difference
24 in the expression of the animal's genes as well as detection of the specific changes
25 (including but not limited to mutations) may unravel the condition in the event that the
26 animal is not healthy, as they age, and as other significant events occur which may
27 affect the animal's overall health. All results from individual analysis device readings
28 will be stored in the biological database for access by the responsible individual or a

1 veterinarian over time.

2 It is also suggested by the present invention that the analysis device may be
3 used for detecting any endemic viral or bacterial gene or other biological expressions
4 occurring in the animal's body, which could result in disease or other malfunction of
5 the body.

6 In addition to tracking expression profiles, by virtue of understanding each
7 animal's gene expression, medications or treatments can be recommended to a
8 responsible individual that will be best suited to change or correct that animal's
9 expression profile or deal with a manifested condition. For example there may be a
10 gene expression, which predisposes an animal to react adversely to certain
11 medications or treatments. Similarly there may be certain protein-drug interactions
12 about which an individual should be wary as the owner of the animal. Thus as part
13 of the interpretation of the gene and other biological expression of the animal,
14 recommendations for medication can be made to the individual. Further, based
15 upon individual gene expression, "targeted" drugs could be designed which work in
16 an optimal fashion for the particular animal, as well as target "preventive" drugs.

17 In addition to whether certain medications could be taken or not, the
18 effectiveness of certain medications also depends upon the gene expression of the
19 animal. In this case information can be provided to a responsible individual as to
20 which medications or treatments that are best suited for that particular animal in a
21 particular situation.

22 From an economic standpoint, responsible individuals will be able to purchase
23 analysis devices 22, 24, and 26 at a reasonable cost once these chips are readily
24 made available to millions of individuals. Each time a reading is interpreted by the
25 genomic processor the responsible individual can be charged for that particular
26 interpretation.

27 Referring to Figure 1A, the analysis device reader 16 in a stand-alone mode
28 (as first noted above) is illustrated. In certain instances and where an individual does
29 not want to have genomic or other biological factor information transmitted over a

1 network, a stand-alone analysis device reader **16** can be used. This analysis device
2 reader uses the analysis device **24** to collect a biological sample. The analysis
3 device **24** is placed in the analysis device receptacle **70**, which is powered by a
4 stand-alone power supply **62**. This power supply can be single use or rechargeable
5 battery supply, and may also be plugged into household current to recharge batteries
6 or to simply power the stand-alone device.

7 The analysis device reader **16** comprises analysis logic **64** for
8 interpreting the analysis device readings. Thereafter, the reading may be stored in a
9 memory **66** in the case where the user wants to have an historical record of readings
10 over a period of time. The analysis device reader **16** also comprises a screen or
11 display **68** for providing a limited readout of the presence of or quantity of the biologic
12 factor or substance being collected by the analysis device **24**. In this fashion, for
13 example, if a particular biological factor is not present, and this is not troubling for the
14 user, the results do not have to be sent over a network and risk a disclosure of the
15 fact that such a test is being conducted by the user. Alternatively, if the results of the
16 readout are such that the user desires to send information, the analysis device
17 reader also comprises a communication port **68** which may be connected to a
18 network for transmitting information stored in memory over the network as described
19 in Figure 1 (above). The display, analysis logic power supply and readout
20 capabilities are generally disclosed in U.S. Patent No. 5,837,546, which is
21 incorporated herein in its entirety. However, the capability to analyze the genetic,
22 proteomic and other biological factors described herein constitutes a novel capability
23 within the current state-of-the-art.

24 By virtue of the memory in the analysis device **16** certain limited expression
25 comparisons can be made from one reading to another. When a difference above a
26 certain threshold occurs between two readings the analysis logic **64** can inform the
27 user of the detection of that difference via the readout / display **68**. Thereafter, if the
28 user chooses that information can be sent to an analysis processor (Figure 3, 12) via

1 the comm. port 68.

2 Referring to Figure 2 the genophone of the present invention is illustrated.
3 The genophone 30 is a form of cellular communications device having its own
4 transceiver 44 connected to the cellular network 45 which in turn subsequently is
5 linked to analysis processor 12 via a wireless application protocol (WAP) gateway 47
6 and thence over the Internet 46 to the analysis site. The characteristics of the WAP
7 gateway are described in U.S. Patent No. 5,327,529, whose contents are
8 incorporated herein by reference in their entirety. The linkage to the analysis
9 processor can also be via the wireless network directly where the analysis center is
10 capable of receiving an electronic signal from the genophone over its own wireless
11 transceiver or alternatively the genophone can ultimately connect to an Internet
12 service provider via a WAP gateway as noted above and electronic information
13 concerning data collected can then be presented to the analysis via the Internet as
14 described earlier.

15 The genophone has a series of cartridges or readers illustrated as sugar
16 reader 32, DNA reader 34, and protein reader 36 although these readers are not
17 meant as limitations. For example it is fully anticipated that as the bio/genomic
18 science becomes more refined, other combination readers having this combinations
19 or others are also anticipated. Each cartridge will have an associated analysis
20 device illustrated as a sugar chip 38, a DNA chip 40 and/or a protein chip 42. As
21 noted earlier, these chips are not meant as a limitation. Analysis for peptides, small
22 molecules, hormones, and metabolites are yet further examples, and are not meant
23 as limiting, of the types of indicators that can be monitored using the present
24 invention.

25 Referring to Figure 3 a kiosk-oriented embodiment of the present invention is
26 illustrated. Central to this embodiment for expression profiling is a form of kiosk 60
27 which would reside in a more or less public area such as a mall, a veterinarian's
28 office, and/or a hospital. In this embodiment a responsible individual possessing a

1 credit card or, preferably, a smart card 62, which would be associated with a credit
2 card issuer such as VISA®, MasterCard® and American Express® would have
3 individualized identification information stored, in encrypted form, on the smart card
4 62. A responsible individual who wishes to establish a control expression profile or
5 to simply create an expression profile at that point in time would use the smart card
6 to begin the over all process of establishing an expression profile in much the same
7 way that an individual now uses a credit card and automated teller machine to begin
8 a financial transaction.

9 The responsible individual would insert the smart card 62 in the kiosk 60.
10 Once the appropriate credit was established with a credit facility 66, which is the
11 normal type of electronic credit transaction that establishes that a responsible
12 individual has a certain amount of credit and has entered the appropriate security
13 information either via a key board or through some biometric measurement, the kiosk
14 60 is permitted to perform further functions.

15 After the kiosk receives the appropriate authorizations from the credit facility
16 for the financial aspect of the transaction, the kiosk provides analysis device 64 to
17 the responsible individual. As noted above the analysis device may be a sugar
18 analysis, DNA analysis, and/or a protein analysis device as appropriate although this
19 is not meant as a limitation. Analysis for peptides, small molecules, hormones, and
20 metabolites also occur. The user deposits a biological sample on the analysis device
21 and reinserts the analysis device into the analysis device reader in the kiosk.
22 Thereafter an analysis device reader in the kiosk reads the information on the
23 analysis device in much the same way that individual cartridges read the chip in the
24 genophone embodiment first noted above. Once the information on the analysis
25 device is read, the digital information, or other transmittable information, which
26 characterizes the biological sample is passed over a network to the analysis
27 processor 12, which creates the desired expression profile. As noted earlier, the
28 kiosk itself may be a cellular or wireless device that communicates with the analysis

1 site in a wireless fashion.

2 Information can be entered by the user at the kiosk regarding the location to
3 which the information is to be sent. Thus the user can specify that resulting
4 information be sent to an associated e-mail address, be sent over the mail system to
5 the user, to be reported via voice or delivered in other ways known to those skilled in
6 the art.

7 Similar to the genophone noted above, the kiosk can also communicate to the
8 analysis center over a cellular or other wireless type network. Thus without
9 limitation, the kiosk can report its results to the analysis via wired network, wireless
10 networks, cellular networks, and other communications methods known in the trade
11 including satellite communications as well.

12 Encryption of the resulting data can be accomplished by an appropriate
13 encryption key stored on the smart card of the responsible individual and conveyed
14 to the kiosk for subsequent encryption to the analysis center.

15 As part of the database operations of the present invention, individual
16 expression profile information in a secure fashion. In addition, once specific
17 conditions are assessed by virtue of expression profile comparison, the analysis
18 processor of the present invention will review all files in its database and send the
19 latest health news that relates to the diseases or conditions evidenced by the
20 expression profiles stored in the database. In this fashion, and individual with, for
21 example, diabetes, can receive the latest information that breaks relating to this
22 condition or on the latest equipment available for maintaining a healthy state. Such
23 information can be delivered via pager, wireless telephone, PDA, and or email.

24 The organization that is responsible for the analysis processor will also
25 receive notices of research projects requiring test subjects. When such notice is
26 given, the database of the present invention be searched and, if authorized by the
27 affected individual, those whose conditions are to be the subject of such medical
28 research will be provided notice of the need for test subjects. Again, in this fashion
29 the database will be able to alert those with specific conditions or expression profiles

1 of the opportunity to participate in such studies.

2 The ramifications of this invention are significant. For example, while DNA,
3 protein, mRNA, sugars and the like have been mentioned as items to be monitored,
4 so can small molecules, peptides, hormones and metabolites. These items will also
5 serve to establish a baseline when the individual is healthy and can later be
6 monitored as potential precursors to a disease state(s).

7 Further, as the monitoring of the present invention takes place, the information
8 gleaned can be stored in an anonymous way in a database so that individual
9 variation can be interpreted not just with respect to other measurements from the
10 same individual, but can also be interpreted in the context of larger demographic
11 results.

12 Additionally, monitoring of those individuals undergoing therapy of various
13 types is very important where there is a possibility of an adverse drug reaction or
14 where a narrow therapeutic range is desirable for the drug in question. Real time
15 monitoring of various indicators as noted in the present invention can help to avoid
16 such adverse drug reactions.

17 A genome and biological factor assessment apparatus and method in
18 alternate embodiments has now been shown. It will be apparent to those skilled in
19 the art that other applications and businesses can benefit from this model of DNA
20 chip reading and genome information storage without departing from the scope of
21 the invention as disclosed.
22

1 I claim:

- 2 1. A system for genomic and proteomic animal disease assessment via
3 expression profile comparison comprising:
4 a first analysis device for establishing an expression profile and on which is
5 deposited a first biological sample from an animal;
6 An analysis device reader for reading biological information from the first
7 biological sample;
8 a first network connected to the analysis device reader for transmitting the
9 biological information;
10 an analysis processor connected to the network for receiving the biological
11 information;
12 storage connected to the analysis processor for storing the biological
13 information and for storing baseline expression information; and
14 instructions stored in the analysis processor for comparing the stored
15 biological information to subsequent biological information.
- 16 2. The system for genomic and proteomic animal disease assessment via
17 expression profile comparison of claim 1 wherein the biological information
18 is proteomic information.
- 19 3. The system for genomic and proteomic animal disease assessment via
20 expression profile comparison of claim 1 wherein the biological information
21 is genomic information.
- 22 4. The system for genomic and proteomic animal disease assessment via
23 expression profile comparison of claim 1 wherein the biological information
24 is genomic information and is taken from the group consisting of DNA and
25 RNA.
- 26 5. The system for genomic and proteomic animal disease assessment via
27 expression profile comparison of claim 1 wherein the biological information
28 is information concerning sugars in the biological sample.
- 29 6. The system for genomic and proteomic animal disease assessment via

1 expression profile comparison of claim 1 wherein subsequent biological
2 information comprises a subsequent biological sample from the animal
3 deposited on a subsequent analysis device at a date subsequent to the
4 deposit of first biological sample.

5 7. The system for genomic and proteomic animal disease assessment via
6 expression profile comparison of claim 1 wherein the analysis device
7 reader is connected to the network via a personal computer.

8 8. The system for genomic and proteomic animal disease assessment via
9 expression profile comparison of claim 1 wherein the analysis device
10 reader is connected to the network via a wireless device.

11 9. The system for genomic and proteomic animal disease assessment via
12 expression profile comparison of claim 8 wherein the wireless device is a
13 genophone.

14 10. The system for genomic and proteomic animal disease assessment via
15 expression profile comparison of claim 9 wherein the genophone
16 comprises an analysis device reader and a wireless transceiver connected
17 to a second network for transmitting the biological information in a wireless
18 mode to the first network.

19 11. The system for genomic and proteomic animal disease assessment via
20 expression profile comparison of claim 1 wherein the first network is a
21 wireless network.

22 12. The system for genomic and proteomic animal disease assessment via
23 expression profile comparison of claim 1 wherein the analysis device
24 reader is located in a kiosk and wherein the kiosk is connected to a credit
25 facility for processing credit request for use of the analysis device reader.

26 13. The system for genomic and proteomic animal disease assessment via
27 expression profile comparison of claim 12 wherein access to the kiosk is
28 made via a token associated with a particular user.

29 14. The system for genomic and proteomic animal disease assessment via

1 expression profile comparison of claim 13 wherein the token is a smart
2 card.

3 15. The system for genomic and proteomic animal disease assessment via
4 expression profile comparison of claim 13 wherein the token is a credit
5 card.

6 16. The system for genomic and proteomic animal disease assessment via
7 expression profile comparison of claim 13 wherein the token is a stored
8 value card.

9 17. The system for genomic and proteomic animal disease assessment via
10 expression profile comparison of claim 1 wherein instructions stored in the
11 analysis processor further comprise instructions for creating a first
12 expression profile from the biological information.

13 18. The system for genomic and proteomic animal disease assessment via
14 expression profile comparison of claim 17 wherein instructions stored in
15 the analysis processor further comprise instructions for creating a
16 subsequent expression profile from the subsequent biological information
17 and for comparing the first expression profile to the subsequent expression
18 profile to detect disease and genetic conditions.

19 19. A method of genomic and proteomic animal disease assessment via
20 expression profile comparison comprising:
21 establishing a baseline expression profile at a first date;
22 storing the expression profile in an analysis center;
23 creating a subsequent expression profile at a date later than that of the
24 baseline expression profile;
25 comparing the subsequent expression profile to the baseline expression
26 profile; and
27 assessing medical conditions based upon the comparison.

28 20. The method of genomic and proteomic animal disease assessment via
29 expression profile comparison of claim 19 wherein establishing a baseline

1 expression profile comprises depositing a biological sample on a first
2 analysis device;
3 reading the analysis device in an analysis device reader; and
4 transmitting the analysis device reader results over a network to an
5 analysis center.

6 21. The method of genomic and proteomic animal disease assessment via
7 expression profile comparison of claim 20 wherein the network is the
8 Internet.

9 22. The method of genomic and proteomic animal disease assessment via
10 expression profile comparison of claim 20 wherein the network is a
11 wireless network.

12 23. The method of genomic and proteomic animal disease assessment via
13 expression profile comparison of claim 20 wherein the analysis device
14 reader is connect to a personal computer; and wherein the personal
15 computer is connected to the network.

16 24. The method of genomic and proteomic animal disease assessment via
17 expression profile comparison of claim 20 wherein the analysis device
18 reader is a wireless device for reading the analysis device and for
19 transmitting the analysis device reader results in a wireless mode to the
20 analysis center.

21 25. The method of genomic and proteomic animal disease assessment via
22 expression profile comparison of claim 20 wherein the biological sample is
23 taken from the group consisting of saliva, blood and urine.

24 26. The method of genomic and proteomic animal disease assessment via
25 expression profile comparison of claim 19 wherein the analysis device
26 reader results comprise genomic information.

27 27. The method of genomic and proteomic animal disease assessment via
28 expression profile comparison of claim 19 wherein the analysis device
29 reader results comprise proteomic information.

- 1 28. The method of genomic and proteomic animal disease assessment via
2 expression profile comparison of claim 19 wherein the analysis device
3 reader results comprise sugars in the biological sample.
- 4 29. The method of genomic and proteomic animal disease assessment via
5 expression profile comparison of claim 19 wherein creating a subsequent
6 expression profile comprises depositing a biological sample on a
7 subsequent analysis device;
8 reading the subsequent analysis device in an analysis device reader; and
9 transmitting the analysis device reader results for the subsequent analysis
10 device over a network to the analysis center.
- 11 30. The method of genomic and proteomic animal disease assessment via
12 expression profile comparison of claim 20 wherein the analysis comprises
13 instructions stored in memory for comparing the subsequent expression
14 profile to the baseline expression profile.
- 15 31. The method of genomic and proteomic animal disease assessment via
16 expression profile comparison of claim 20 wherein the analysis device
17 reader is located in a kiosk and wherein the kiosk is connected to a credit
18 facility for processing credit request for use of the analysis device reader.
- 19 32. The method of genomic and proteomic animal disease assessment via
20 expression profile comparison of claim 20 wherein the kiosk is made
21 available via a token associated with a particular user.
- 22 33. The method of genomic and proteomic animal disease assessment via
23 expression profile comparison of claim 20 wherein the token is a smart
24 card.
- 25 34. The method of genomic and proteomic animal disease assessment via
26 expression profile comparison of claim 20 wherein the token is a credit
27 card.
- 28 35. The method of genomic and proteomic animal disease assessment via
29 expression profile comparison of claim 20 wherein the token is a stored

1 value card.

2 36. The method of genomic and proteomic animal disease assessment via
3 expression profile comparison of claim 20 wherein the biological
4 information is genomic information and is taken from the group consisting
5 of DNA and mRNA.

6 37. The method of genomic and proteomic animal disease assessment via
7 expression profile comparison of claim 19 wherein the analysis device
8 reader results comprise hormones.

9 38. The method of genomic and proteomic animal disease assessment via
10 expression profile comparison of claim 19 wherein the analysis device
11 reader results comprise peptides.

12 39. The method of genomic and proteomic animal disease assessment via
13 expression profile comparison of claim 19 wherein the analysis device
14 reader results comprise metabolites.

15 40. The method of genomic and proteomic animal disease assessment via
16 expression profile comparison of claim 19 wherein the analysis device
17 reader results comprise enzymes.

18 41. The method of genomic and proteomic animal disease assessment via
19 expression profile comparison of claim 19 wherein the analysis device
20 reader results comprise antibodies.

21 42. The method of genomic and proteomic animal disease assessment via
22 expression profile comparison of claim 20 wherein the analysis device is a
23 microarray.

24 43. The method of genomic and proteomic animal disease assessment via
25 expression profile comparison of claim 20 wherein the analysis device is a
26 fiber optic probe comprising a plurality of sensors.

27 44. The method of genomic and proteomic animal disease assessment via
28 expression profile comparison of claim 20 wherein the analysis device is a
29 semiconductor microchip.

- 1 45. The method of genomic and proteomic animal disease assessment via
2 expression profile comparison of claim 20 wherein the analysis device is a
3 cartridge comprising a semiconductor microchip.
- 4 46. The method of genomic and proteomic animal disease assessment via
5 expression profile comparison of claim 20 wherein the analysis device
6 utilizes electron concentration and hybridization technology.
- 7 47. The method of genomic and proteomic animal disease assessment via
8 expression profile comparison of claim 20 wherein the analysis device
9 comprises a microfabricated capillary electrophoresis chip.
- 10 48. The method of genomic and proteomic animal disease assessment via
11 expression profile comparison of claim 20 wherein the analysis device
12 comprises a centripetal acceleration microsystem platform.
- 13 49. The system for genomic and proteomic animal disease assessment via
14 expression profile comparison of claim 1 wherein the biological
15 information is hormonal information.
- 16 50. The system for genomic and proteomic animal disease assessment via
17 expression profile comparison of claim 1 wherein the biological
18 information is peptide information.
- 19 51. The system for genomic and proteomic animal disease assessment via
20 expression profile comparison of claim 1 wherein the biological
21 information is metabolite information.
- 22 52. The system for genomic and proteomic animal disease assessment via
23 expression profile comparison of claim 1 wherein the biological
24 information is enzyme information.
- 25 53. The system for genomic and proteomic animal disease assessment via
26 expression profile comparison of claim 1 wherein the biological
27 information is antibody information.
- 28 54. The system for genomic and proteomic animal disease assessment via
29 expression profile comparison of claim 1 wherein the analysis device is a

1 microarray.

2 55. The system for genomic and proteomic animal disease assessment via
3 expression profile comparison of claim 1 wherein the analysis device is a
4 fiberoptic probe comprising a plurality of sensors.

5 56. The system for genomic and proteomic animal disease assessment via
6 expression profile comparison of claim 1 wherein the analysis device is a
7 semiconductor chip.

8 57. The system for genomic and proteomic animal disease assessment via
9 expression profile comparison of claim 1 wherein the analysis device is a
10 cartridge comprising a semiconductor chip.

11 58. The system for genomic and proteomic animal disease assessment via
12 expression profile comparison of claim 1 wherein the analysis device
13 comprises electronic concentration and hybridization technology.

14 59. The system for genomic and proteomic animal disease assessment via
15 expression profile comparison of claim 1 wherein the analysis device is a
16 microfabricated capillary electrophoresis chip.

17 60. The system for genomic and proteomic animal disease assessment via
18 expression profile comparison of claim 1 wherein the analysis device
19 comprises a centripetal acceleration microsystem platform.

20 61. A system for genomic and proteomic animal disease assessment via
21 expression profile determination comprising:
22 an analysis device for collecting a biological sample;
23 an analysis device reader adapted to create a reading from the analysis
24 device, the analysis device reader comprising;
25 an analysis device receptacle for receiving and creating the analysis
26 device reading from the contents of the analysis device;
27 a power supply connected to the analysis device receptacle for providing
28 power to the receptacle;
29 a processor comprising analysis logic for receiving the results of the

1 reading from the analysis device and for creating a record of the results;
2 memory connected to the analysis processor for receiving the record of the
3 results; and

4 a display connected to the processor for displaying the record of results.

5 62. The system for genomic and proteomic animal disease assessment via
6 expression profile determination of claim 61 wherein the record of results
7 comprises a first expression profile.

8 63. The system for genomic and proteomic animal disease assessment via
9 expression profile determination of claim 62 wherein the processor further
10 comprises logic for comparing the first expression profile to a second
11 expression profile and for alerting a user via the display of the presence of
12 any differences between the expression profile and the subsequent
13 expression profile.

14 64. The system for genomic and proteomic animal disease assessment via
15 expression profile determination of claim 61 further comprising a
16 communications port for transmitting the record of results over a network.

17 65. The system for genomic and proteomic animal disease assessment via
18 expression profile determination of claim 64 where the network is selected
19 from the group consisting of wireless networks, the Internet, an intranet,
20 and wireless local loop network.

21 66. The system for genomic and proteomic animal disease assessment via
22 expression profile determination of claim 61 wherein the analysis device is
23 adapted to detect hormones and the record of results is hormonal
24 information.

25 67. The system for genomic and proteomic animal disease assessment via
26 expression profile determination of claim 61 wherein the analysis device is
27 adapted to detect peptides and the record of results is peptide information.

28 68. The system for genomic and proteomic animal disease assessment via
29 expression profile determination of claim 61 wherein the analysis device is

1 adapted to detect metabolites and the record of results is metabolite
2 information.

3 69. The system for genomic and proteomic animal disease assessment via
4 expression profile determination of claim 61 wherein the analysis device is
5 adapted to detect enzymes and the record of results is enzyme
6 information.

7 70. The system for genomic and proteomic animal disease assessment via
8 expression profile determination of claim 61 wherein the analysis device is
9 adapted to detect antibodies and the record of results is antibody
10 information.

11 71. The system for genomic and proteomic animal disease assessment via
12 expression profile determination of claim 61 wherein the analysis device is
13 selected from the group consisting of a microarrays, a fiberoptic probe
14 comprising a plurality of sensors, a semiconductor chip, a cartridge
15 comprising a semiconductor chip, an electronic concentration and
16 hybridization technology device, and a microfabricated capillary
17 electrophoresis chip.

18 72. A method of genomic and proteomic animal disease assessment via
19 expression profile determination comprising:
20 establishing a first expression profile at a first date by depositing a
21 biological sample on an analysis device;
22 reading the analysis device in an analysis device reader, the analysis
23 device reader comprising an analysis device receptacle for receiving the
24 analysis device, and analysis processor and associated memory, and
25 interconnected power supply, and display ;
26 analyzing the reading from the analysis device in the analysis processor,
27 displaying the analysis results on the display;
28 storing the analysis results in a memory associated with
29 reading the analysis device processor.

- 1 73. The method of genomic and proteomic animal disease assessment via
2 expression profile determination of claim 72 wherein the biological sample
3 is taken from the group consisting of hormones, peptides, metabolites,
4 enzymes, antibodies, genes proteins sugars, DNA and RNA.
- 5 74. The method of genomic and proteomic agricultural disease assessment
6 via expression profile determination of claim 72 wherein the analysis
7 device is taken fro the group consisting of a microarrays, fiberoptic probe
8 comprising a plurality of sensors, semiconductor chips, cartridges
9 comprising a semiconductor chip, electronic concentration and
10 hybridization technology devices, centripetal acceleration microsystem
11 platforms, and microfabricated capillary electrophoresis chips.
- 12 75. The method of genomic and proteomic agricultural disease assessment
13 via expression profile determination of claim 74 wherein the analysis
14 device is adapted to provide readings from biological samples from the
15 group consisting of hormones, peptides, metabolites, enzymes,
16 antibodies, genes proteins sugars, DNA and RNA.
- 17
18
19

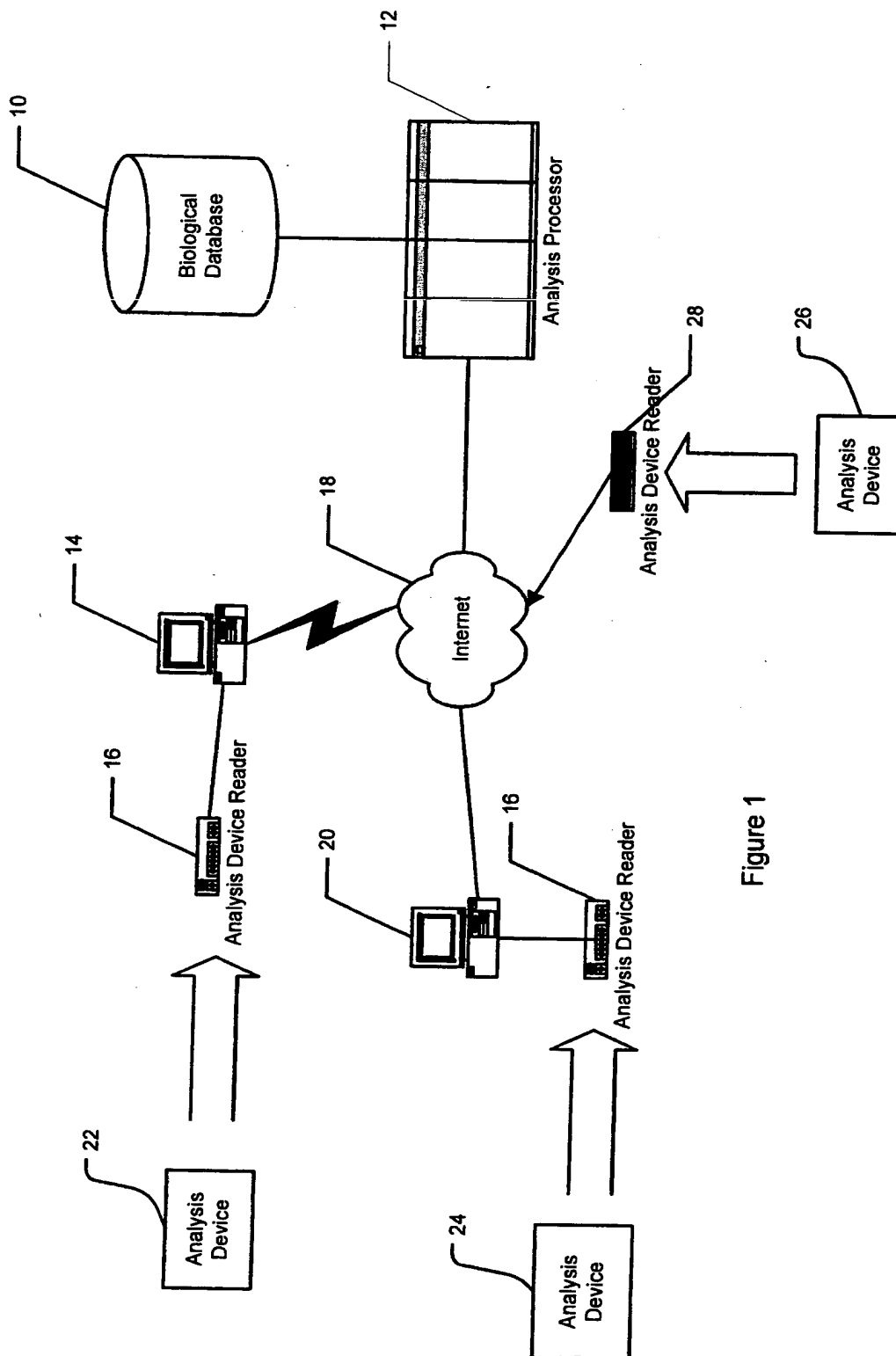
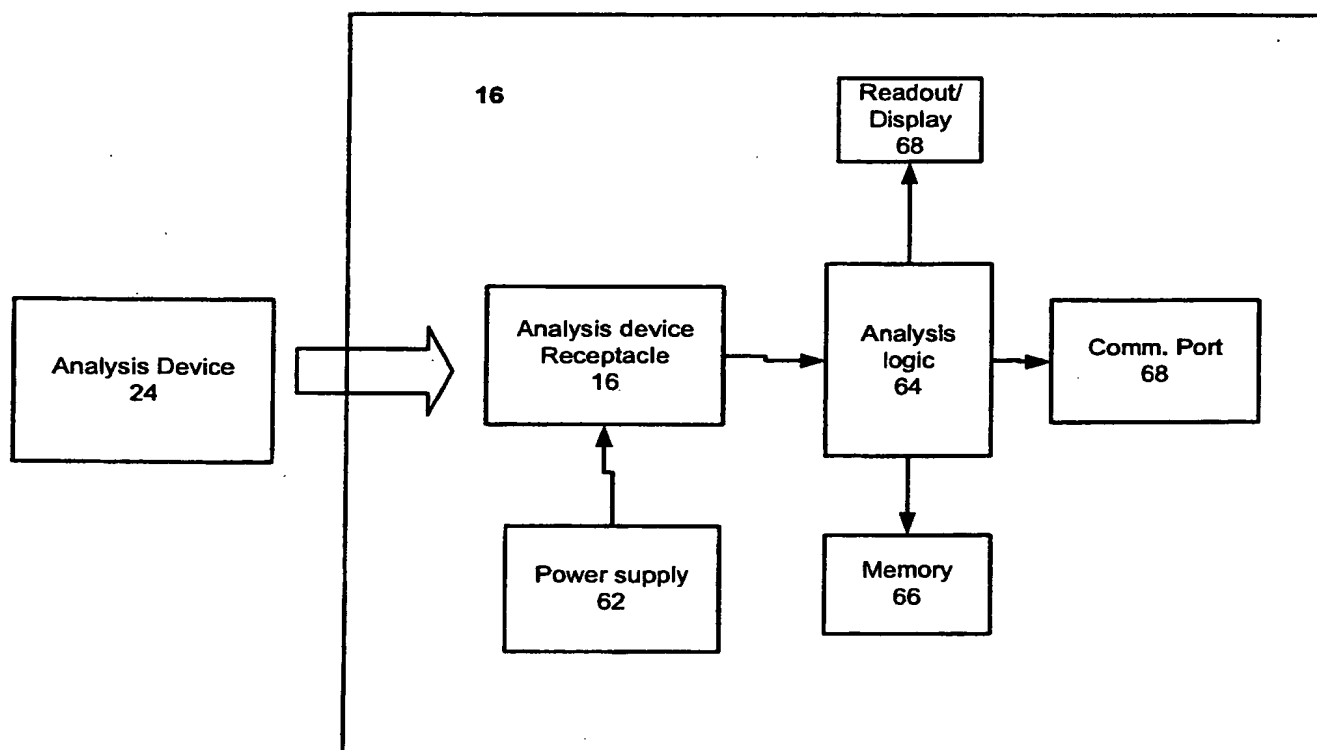


Figure 1

**Figure 1A**

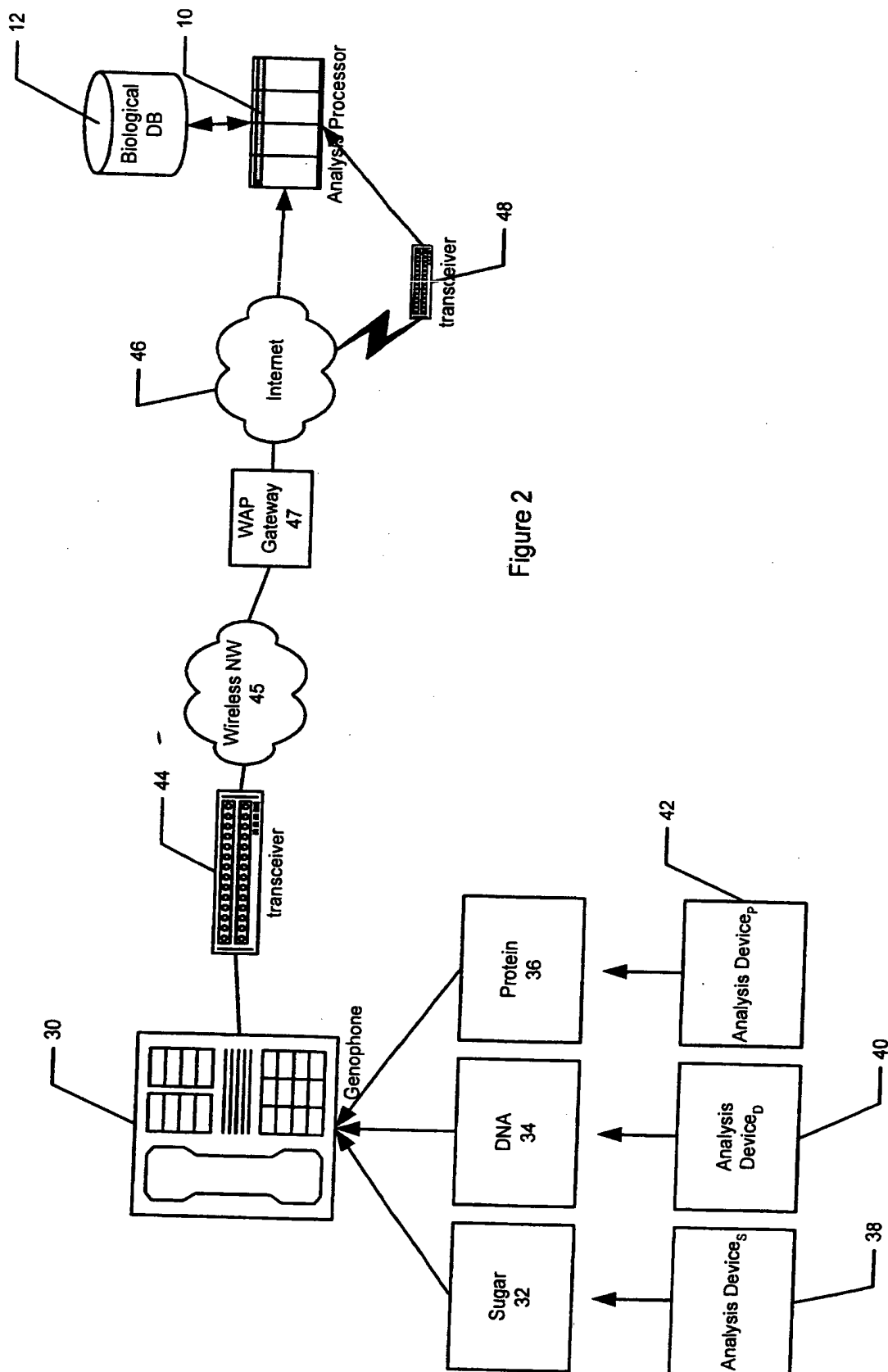


Figure 2

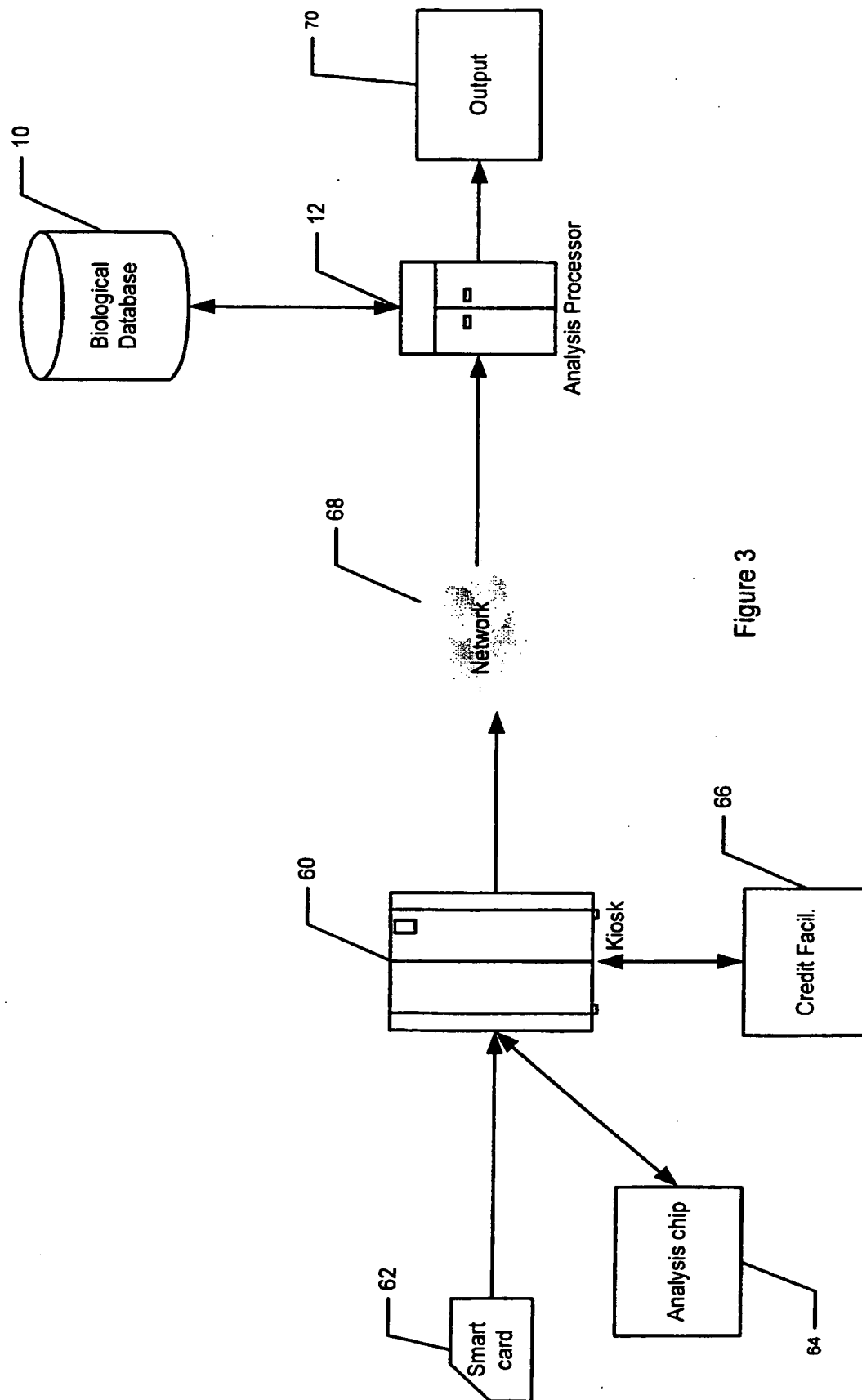


Figure 3

